Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Initially, on the Office Action summary page, the Examiner indicates that the priority document has not been received. Referring to the top of page 2 of the Office Action, the Examiner apparently meant to indicate that an English translation of the priority document has not been received. The Notice of Acceptance indicates that the priority document has been received.

Claim 1 has been amended to incorporate the subject matter of claim 3, as a result of which claims 2 and 3 have been cancelled.

Amended claim 1 also refers to a medically acceptable salt, which is supported by the disclosure at page 13, line 15 of the specification.

Claims 10, 12 and 14-16 have also been cancelled.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 1-9, 11 and 13 under 35 U.S.C. §103(a) as being unpatentable over WO 01/034147 as evidenced by CA 2390933 in view of USP 4,743,249 and Staskin is respectfully traversed.

As the Examiner has noted, the Staskin article discloses a transdermal preparation of oxybutynin having anticholinergic effects, and also discloses that the drug can be used for treating overactive bladders. Oxybutynin is also known as "Pollakisu," an oral preparation.

However, a treatment for increased urinary frequency and urinary incontinence containing KRP-197 disclosed in CA 2390933 (WO 01/034147) is not always applicable to a transdermal preparation as in the case disclosed in the Staskin article.

Most compounds are generally known to show advantageous effects including less liver damage and reduced side effects by transdermal administration. In fact however, they hardly

became commercially available as a transdermal preparation. This is because the active ingredients contained therein are not always suitable for use as a transdermal preparation.

For example, over 10 types of compounds contained in a bronchodilator as oral beta-2 agonists are commercially available (arformoterol tartrate, bambuterol, clenbuterol hydrochloride, dopexamine hydrochloride, fenoterol hydrobromide, formoterol fumarate hydrate, levosalbutamol hydrochloride, mabuterol hydrochloride, pirbuterol hydrochloride, procaterol hydrochloride hydrate, ritodrine hydrochloride, salmeterol xinafoate, terbutaline sulfate, tulobuterol hydrochloride, etc.). Of these, only tulobuterol can be used as a transdermal preparation, and the remaining compounds have been failed to be prepared as a transdermal preparation. This supports Applicants' argument above that the mere fact that a particular drug has been known to be orally effective (like in the CA/WO reference) would not lead one of ordinary skill in the art to expect, with any reasonable degree of certainty, that the same drug would also be effective in a transdermal preparation.

USP 4,743,249 discloses atropine, methscopolamine bromide, and methscopolamine bromide with Phenobarbital used as an antispasmodic agent. However, it does not disclose or suggest 4-(2-methyl-1-imidazolyl)-2,2-diphenylbutylamide as a selective muscarinic M3 and M1 receptor antagonist for use as a treatment for increased urinary frequency and urinary incontinence that occur in patients with overactive bladder.

Accordingly, the inventive transdermal preparation of 4-(2-methyl-1-imidazolyl)-2,2-diphenylbutylamide is not obvious from a combination of the applied references, even if it would occur to one of ordinary skill in the art to actually combine the references.

The rejection of claims 10 and 14-16 under 35 U.S.C. §103(a), as set forth in item 2 beginning on page 3 of the Office Action, has been rendered moot in view of the cancellation of these claims.

Similarly, in view of the cancellation of claim 12, the rejection of this claim under 35 U.S.C. §103(a) in item 3 has also been rendered moot.

The obviousness-type double patenting rejection of claims 1-16 as being unpatentable over claims 1-5 of US 2007/0092566, as well as the rejection of claims 1-16 for obviousness-

type double patenting as being unpatentable over claims 13-26 of US 2008/0107727, are respectfully traversed.

The comments set forth above concerning the rejection of claims 1-9, 11 and 13 under 35 U.S.C. §103(a), are equally applicable to both of these double patenting rejections. That is, the mere fact that a particular drug has been known to be orally effective would not lead one of ordinary skill in the art to expect, with any reasonable degree of certainty, that the same drug would also be effective in a transdermal preparation. Accordingly, Applicants take the position that the double patenting rejections should also be withdrawn.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

The Commissioner is authorized to charge any deficiency or to credit any overpayment associated with this communication to Deposit Account No. 23-0975, with the EXCEPTION of deficiencies in fees for multiple dependent claims in new applications.

Respectfully submitted,

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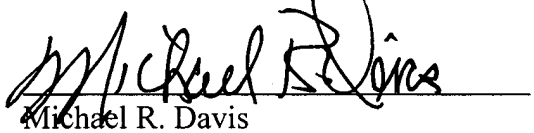
By: 

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